

United States District Court
District of Massachusetts

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FERRING PHARMACEUTICALS, INC.,)	
)	
Plaintiff-Counterclaim)	
Defendant,)	
)	Civil Action No.
v.)	13-12553-NMG
)	
BRAINTREE LABORATORIES, INC.,)	
)	
Defendant-Counterclaim)	
Plaintiff.)	
)	

MEMORANDUM & ORDER

GORTON, J.

This case concerns two pharmaceutical companies that have competing products used for bowel preparation before colonoscopies. Plaintiff/counterclaim-defendant Ferring Pharmaceuticals, Inc. ("Ferring") claims that Defendant/counterclaim-plaintiff Braintree Laboratories, Inc. ("Braintree") engaged in false advertising in violation of the Lanham Act and unfair trade practices in violation of the Massachusetts Consumer Protection Act, M.G.L. ch. 93A ("Chapter 93A"). Ferring also alleges that Braintree diluted Ferring's trademark in its product, Prepopak. Braintree counterclaims that Ferring has, itself, engaged in false advertising and unfair trade practices. In August, 2014, the Court dismissed

Braintree's additional counterclaim that Ferring misappropriated trade secrets.

I. Factual and Procedural Background

Ferring, a Delaware corporation with its principal place of business in Switzerland, advertises and sells Prepopik, a colonoscopy preparation medication. Braintree, a Massachusetts corporation with its principal place of business in Braintree, Massachusetts, advertises and sells Suprep which is similarly used prior to colonoscopies.

In October, 2013, Ferring filed a complaint against Braintree which, in turn, answered and counterclaimed. In August, 2014, this Court allowed Ferring's motion to dismiss Braintree's counterclaims that Ferring had misappropriated trade secrets and falsely advertised with respect to "flexible dosing" and "helps achieve success." The Court denied Ferring's motions to dismiss Braintree's false advertising counterclaims relating to "superior cleansing efficacy" and "lowest volume." The Court also denied Braintree's motion for summary judgment without prejudice.

On April 22, 2016, Ferring filed motions for summary judgment on Braintree's counterclaims, its own Canadian Adverse Reaction Newsletter ("Canadian Newsletter") and "What's NOT New About Prepopik" ("comparison detailer") claims and Braintree's affirmative defenses. Braintree, in turn, filed its own motion

for summary judgment on all of Ferring's claims. The motions for summary judgment are pending before the Court.

II. Motions for Summary Judgment

A. Legal Standard for Summary Judgment

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991). The burden is on the moving party to show, through the pleadings, discovery and affidavits, "that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material if it "might affect the outcome of the suit under the governing law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A genuine issue of material fact exists where the evidence with respect to the material fact in dispute "is such that a reasonable jury could return a verdict for the nonmoving party." Id.

If the moving party has satisfied its burden, the burden shifts to the non-moving party to set forth specific facts showing that there is a genuine, triable issue. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The Court must view the entire record in the light most favorable to the non-moving party and indulge all reasonable inferences in that party's favor. O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993).

Summary judgment is appropriate if, after viewing the record in the non-moving party's favor, the Court determines that no genuine issue of material fact exists and that the moving party is entitled to judgment as a matter of law.

B. Motions for Summary Judgment on Ferring's Lanham Act and Chapter 93A Claims

Both parties move for summary judgment on Ferring's claims that Braintree's use of the Canadian Newsletter and comparison detailer constituted false or misleading advertising under the Lanham Act and violated Chapter 93A. Braintree also moves for summary judgment on Ferring's "Clean Freak" claim.

1. Legal Standard

The Lanham Act prohibits "commercial advertising or promotion" that "misrepresents the nature, characteristics, [or] qualities" of a product. 15 U.S.C. § 1125(a)(1)(B). To prevail on a claim brought under that statute, a plaintiff must prove:

(1) the defendant made a false or misleading description of fact or representation of fact . . . in a commercial advertisement about [its] own or another's product; (2) the misrepresentation is material . . . ; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284 F.3d

302, 310-11 (1st Cir. 2002), cert. denied, 537 U.S. 1001 (2002).

There are two paths to success on a Lanham Act claim. A plaintiff can show that an advertisement is "literally false" in which case consumer deception is presumed. Clorox Co. Puerto Rico v. Proctor & Gamble Commercial Co., 228 F.3d 24, 33 (1st Cir. 2000). Consumer deception is also presumed if a plaintiff demonstrates an intentional attempt to confuse consumers. Cashmere, 284 F.3d. at 314, 16. Alternatively, a plaintiff may show that an advertisement is "literally true or ambiguous" but misleads consumers. Chlorox, 288 F.3d at 33. For misleading advertisements, a plaintiff must prove that consumers were actually misled which is commonly accomplished through consumer surveys. Id. at 36.

An advertisement is considered material under the Lanham Act if it is "likely to influence the purchasing decision." Cashmere, 284 F.3d. at 311. The materiality requirement is also met if the statement concerns one of the product's "inherent characteristic[s]." Id. at 312.

To have standing to pursue a Lanham Act claim, a plaintiff must demonstrate that it is within the zone of interests protected by § 1125(a) by

alleg[ing] injury to a commercial interest in reputation or sales.

Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1390 (2014). Furthermore, a plaintiff must show that

the defendant's false or misleading promotion proximately caused financial or reputational damage. Id. at 1391.

2. Canadian Adverse Reaction Newsletter

a. Relevant Background

In addition to Prepopik, Ferring produces a chemically-identical treatment called "Pico-Salax" which is sold in other countries. After the Food and Drug Administration ("FDA") approved Prepopik, Ferring issued a press release stating that:

Ferring has a long history in the international gastroenterology market, where PREPOPIK is available in Canada (marketed under the name PICO-SALAX)

Although Prepopik and Pico-Salax have the same chemical composition, there are several purported differences between the treatments. Prepopik must be prescribed but Pico-Salax is available over the counter. The Prepopik instructions direct users to consume approximately two liters of fluid, while the Pico-Salax instructions indicate that users should consume three to four liters of fluid. Furthermore, Prepopik is only approved for adult colonoscopy preparation, whereas Pico-Salax is approved for children and adults in preparation for x-rays, surgeries and colonoscopies.

The Canadian government published an article about Pico-Salax in January, 2013, in the Canadian Adverse Reaction Newsletter, Vol. 23, Issue 1. The Canadian Newsletter states

The diarrhea produced by [Pico-Salax] can lead to dehydration and loss of electrolytes, particularly sodium which may result in hyponatremia and convulsions As of June 30, 2012, Health Canada received 11 reports of convulsions suspected of being associated with Pico-Salax.

Ferring contends that, in violation of the Lanham Act and Chapter 93A, Braintree used the Canadian Newsletter to make false and misleading statements about Prepopik. Both parties move for summary judgment on that claim.

b. Ferring

With respect to Ferring's motion for summary judgment, a genuine issue of material fact remains as to whether Braintree's use of the Canadian Newsletter was false or misleading. Ferring submits that Braintree's use of the letter to raise safety concerns about Prepopik was literally false because the letter concerns Pico-Salax, a different treatment, and does not indicate that Pico-Salax is dangerous. In response, Braintree offers evidence that Ferring's own statements equated Prepopik and Pico-Salax. Braintree also contends that, when the amount of additional hydration that Ferring's own expert, Dr. Gerald Bertiger, recommends patients use with Prepopik is considered, the appropriate hydration for Prepopik and Pico-Salax is almost identical.

Given the conflicting evidence as to whether Prepopik and Pico-Salax are equivalent, a genuine issue of material fact persists as to whether Braintree's use of the letter to point

out safety concerns was literally false. Consequently, such an issue also persists as to whether there is a presumption of consumer deception. See Cashmere, 284 F.3d at 314-15.

c. Braintree

Braintree's motion is similarly jeopardized by the genuine issue of material fact that remains as to whether the use of the newsletter by Braintree employees was false or misleading. It is clear that Braintree employees made extensive use of the Canadian Newsletter but there is conflicting evidence as to whether it was used to highlight potential safety concerns or to support misleading claims, such as statements that Prepopik is "deadly" and "kills people."

Accordingly, the Court will deny both parties' motions for summary judgment with respect to the Lanham Act claim involving the Canadian Newsletter. Because claims under the Lanham Act and Chapter 93A rise and fall together, the Court will also deny both parties' motions for summary judgment as to the Canadian Newsletter Chapter 93A claim. Empire Today, LLC v. Nat'l Floors Direct, Inc., 788 F. Supp. 2d 7, 26 (D. Mass. 2011) ("To establish a false advertising claim under Chapter 93A, a plaintiff must prove all of the elements of a false advertising claim under Section 43(a) of the Lanham Act.").

3. Comparison Detailer

a. Background

The comparison detailer is an FDA-approved flier that Braintree distributed to doctors' offices. Across the top it stated "What's NOT New About Prepopik?" It then listed Prepopik characteristics that are purportedly not new, such as the formula, the acceptability of use for patients with severely reduced renal function and the effect of antibiotics on efficacy. The flyer also compared the price of Prepopik with other bowel preparation treatments, including Suprep.

b. Ferring

Ferring's summary judgment motion cannot prevail because genuine issues of material fact remain as to whether the comparison detailer was misleading.

Ferring asserts that efficacy percentages associated with the comparison detailer are establishment claims that are not backed by reliable studies. In contrast to broad assertions of superiority, establishment claims state that "tests or studies prove a certain fact." Gillette Co. v. Norelco Consumer Prod. Co., 946 F. Supp. 115, 121 (D. Mass. 1996) (internal quotation omitted). To show that an establishment claim is literally false, a plaintiff must show that the study at issue did not support the claim or was unreliable. Id.

During discovery, Ferring unearthed only two instances of the comparison detailer being associated with efficacy percentages: 1) a handwritten annotation on a flyer that stated "plus only 74% efficacy compared to 98% with Suprep!" and 2) a sales log entry that indicated that the comparison detailer had been used along with a statement that

only 84% of patients had successful clean outs taking [Prepopik] compared to 98% of [Suprep] patients.

The Lanham Act applies only if advertisements are distributed to "the consuming public." Ass'n, Inc. v. La Cruz Azul De Puerto Rico, Inc., 332 F.3d 6, 19 (1st Cir. 2003); see also Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc., 314 F.3d 48, 58 (2d Cir. 2002) (determining that 27 oral statements did not constitute commercial advertising under the Lanham Act).

The two instances in which Braintree employees associated the comparison detailer with efficacy percentages are inadequate to show that the efficacy percentages were distributed to the consuming public. Accordingly, Ferring is incorrect in its contention that Braintree's use of the comparison detailer is an establishment claim.

As for the information actually included in the comparison detailer, Ferring does not submit evidence that shows that those statements are literally false. Instead, Ferring asserts that the omission of material information as to Suprep's safety was

misleading and the detailer lacked fair balance. See Gillette Co., 946 F. Supp. at 131.

Because Ferring claims that the text printed in the comparison detailer is misleading, Ferring must also provide either evidence that the comparison detailer was intentionally misleading or that it actually misled consumers. Cashmere, 284 F.3d at 316. Ferring submits that the study conducted by Braintree's expert, Robert Klein, demonstrates that the comparison detailer conveyed the misleading message that Prepopik was unsafe. Braintree, of course, contests that interpretation of its expert's study. Given the contested evidence about whether the comparison detailer misled consumers, Ferring is not entitled to summary judgment on that claim.

c. Braintree

Braintree also moves for summary judgment on the comparison detailer claim. When the facts are viewed in the light most favorable to Ferring, a genuine issue of material fact persists as to whether the comparison detailer was misleading, thereby jeopardizing Braintree's motion.

Given that summary judgment on the Lanham Act comparison detailer claim is unwarranted, the Court will also deny judgment on the Chapter 93A claim. Empire Today, 788 F. Supp. 2d at 26.

4. Clean Freak Advertisement

a. Relevant Background

Braintree moves for summary judgment on Ferring's claim that the following statements in the "Clean Freak" advertisement violate the Lanham Act and Chapter 93A:

Suprep Bowel Prep Kit achieved 'excellent' bowel cleansing in patients based on investigator grading . . .
Significantly more patients had 'excellent' preps with SUPREP Bowel Prep Kit compared to MoviPrep[.]

Those statements are based on two studies that Braintree conducted.

b. Analysis

Braintree is entitled to summary judgment on the Clean Freak claim because that claim is not within the zone of interests that the Lanham Act protects. The United States Supreme Court laid out the requirements that plaintiffs must meet in order to have standing to pursue a false advertising claim under the Lanham Act in Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377 (2014). First, in order to be within the zone of interests protected by that statute, a plaintiff must show that the deceptive advertising financially injured its sales or reputation. Id. at 1390. Second, a plaintiff must show proximate cause, specifically "economic or reputational injury" that is a direct result of the false advertising. Id. at 1391.

In the present case, the Clean Freak advertisement never mentions Prepopik. Instead, it compares Suprep to Moviprep, a different treatment. Ferring does not quibble about the non-reference but directs the Court's attention to five instances where Braintree employees referred to the Clean Freak advertisement in sales conversations that also addressed Prepopik's efficacy. Those examples are insufficient to show that Ferring suffered any financial or reputational harm as a direct result of Braintree's advertising. Indeed, there is a discontinuity between the treatment targeted by the advertisement, Moviprep, and the party alleging injury here, Ferring, the producer and promoter of Prepopik. Even when the undisputed facts are construed in the light most favorable to Ferring, it has failed to show a direct injury arising from the Clean Freak promotion. Consequently, Ferring lacks standing to make such a claim.

Moreover, even assuming arguendo that Ferring has standing, the five isolated instances of Braintree employees mentioning the Clean Freak advertisement in connection with Prepopik is insufficient to show that the promotion was publicly distributed as an advertisement or promotion. See Podiatrist Ass'n, Inc. 332 F.3d at 19. Braintree is entitled to judgment on the Clean Freak claim as a matter of law.

For the same reasons mentioned above, Braintree is also entitled to summary judgment on Ferring's Chapter 93A claims with respect to the Clean Freak advertisement. Empire Today, 788 F. Supp. 2d at 26.

C. Braintree's Motion for Summary Judgment on Ferring's State Trademark Dilution Claim

1. Legal Standard

Massachusetts General Laws, Chapter 110H ("Chapter 110H") entitles the holder of a mark registered pursuant to that chapter to obtain injunctive relief if there is a

[l]ikelihood of injury to business reputation or of dilution of the distinctive quality of a mark

M.G.L. ch. 110H, § 13. To prove trademark dilution pursuant to Chapter 110H, a plaintiff must demonstrate that 1) its mark is distinctive and 2) the defendant's use of a similar mark creates a possibility of dilution. Astra Pharm. Prods., Inc. v. Beckman Instruments, Inc., 718 F.2d 1201, 1209 (1st Cir. 1983). The plaintiff must also show that there is a "distinctive trade name such as a coined word" that has "acquired a distinctive secondary meaning." PPG Indus., Inc. v. Clinical Data, Inc., 620 F. Supp. 604, 606 (D. Mass. 1985).

2. Analysis

Ferring claims that Braintree has diluted its trademark in Prepopik by comparing Prepopik to another Ferring product, Pico-Salax. Braintree responds that Ferring, itself, has equated

Prepopik and Pico-Salax. Indeed, when the FDA first approved Prepopik, Ferring issued a press release stating that

PREPOPIK is available in Canada (marketed under the name PICO-SALAX). . . .

On its website, Ferring even combines the names of Prepopik and Pico-Salax into one word "PICOPREP," lists both Prepopik and Pico-Salax under "PICOPREP" and identifies the ingredients of both as "sodium picosulphate, magnesium oxide, and citric acid." Ferring does not dispute Braintree's argument.

Given Ferring's own equating of Prepopik to Pico-Salax, Prepopik has no distinctive trade name or secondary meaning in relation to Pico-Salax. Braintree is entitled summary judgment on the trademark dilution claim.

D. Ferring's Motion for Summary Judgment on Braintree's Affirmative Defenses

Ferring contends it is entitled to summary judgment on all of Braintree's affirmative defenses. Ferring specifically addresses Braintree's unclean hands defense, asserting that Braintree's allegations of bad faith do not relate to Ferring's affirmative claims and that Braintree has failed to submit evidence that Ferring's conduct was unconscionable, rises to the level of fraud or was done in bad faith.

The doctrine of unclean hands provides a broad defense when the acts at issue

in some measure affect the equitable relations between the parties in respect of something brought before the court for adjudication.

Texaco Puerto Rico, Inc. v. Dep't of Consumer Affairs, 60 F.3d 867, 880 (1st Cir. 1995) (internal quotation and citation omitted). When viewed in the light most favorable to Braintree, Ferring's alleged 1) act of equating Prepopik and Pico-Salax, 2) claim of superior cleansing efficacy and 3) off-label promotion suffice to preserve a genuine issue of material fact as to whether the equitable relations of the parties were affected.

Ferring also makes a conclusory assertion that there are no issues of material fact as to Braintree's 13 other affirmative defenses because no evidence has been uncovered to support them and Braintree's Fed. R. Civ. P. 30(b)(6) witness was not familiar with them. Braintree is, however, correct in its contention that Rule 30(b)(6) witnesses are not required to testify as to alleged affirmative defenses. Neponset Landing Corp. v. Nw. Mut. Life Ins. Co., 279 F.R.D. 59, 61 (D. Mass. 2011).

Ferring offers no other evidence to justify summary judgment on Braintree's affirmative defenses. Consequently, the Court will deny Ferring's motion for summary judgment thereon.

E. Ferring's Motion for Summary Judgment on Braintree's Lanham Act and Chapter 93A Counterclaims

Ferring moves for summary judgment on Braintree's Lanham Act and Chapter 93A counterclaims as to the "lowest volume" and "superior cleansing efficacy" promotions.

1. "Lowest Volume"

Braintree counterclaims that Ferring's advertisement that Prepopik has the "lowest volume of active ingredient" is false or misleading. Ferring moves for summary judgment on that counterclaim on the grounds that the promotion is true. Ferring also contends that Braintree failed to show that the promotion is misleading or involves material information and that Braintree lacks standing.

When viewed in the light most favorable to Braintree, genuine issues of material fact persist as to whether Ferring's lowest volume promotion is literally false. Literal falsity involves two questions of fact: 1) what claim was actually made and 2) whether the claim was false. Clorox Co., 228 F.3d at 34.

As Braintree has pointed out, a fact finder could interpret Ferring's lowest volume claim as invoking a comparison to the entire market of bowel preparation treatments, including tablets which have a lower volume than Prepopik. Furthermore, emails from Ferring employees, internal Ferring documents and Ferring's own expert, Dr. Gerald Bertiger, all acknowledge that additional

hydration is needed, including hydration with liquids containing electrolytes, in order for Prepopik to work effectively.

Consequently, when the evidence is viewed in the light most favorable to Braintree, a genuine issue of material fact remains as to whether the lowest volume claim is literally false.

Braintree has also shown that Ferring's claim of the lowest volume of active ingredient is material because it involves an essential characteristic of Prepopik and because Ferring aggressively marketed Prepopik as being low volume. Cashmere, 284 F.3d at 312. As for causation, because the evidence is viewed in the light most favorable to the non-moving party, Dr. Epstein's report regarding financial damages to Braintree suffices to preserve a genuine issue of material fact. See Lexmark, 134 S. Ct. at 1390-91. Therefore, summary judgment on Braintree's lowest volume counterclaim is precluded and summary judgment on Braintree's Chapter 93A counterclaim will also be denied. Empire Today, 788 F. Supp. 2d at 26.

2. "Superior Cleansing Efficacy"

Ferring moves for summary judgment on Braintree's false advertising counterclaim with respect to the former promotion that Prepopik has "superior cleansing efficacy." Ferring contends that Braintree has failed to demonstrate that the superior cleansing efficacy promotion is false or misleading. According to Ferring, the superior cleansing efficacy promotion

is an establishment claim because it specifically cited the SEE CLEAR I study. See Gillette Co., 946 F. Supp. at 121. To demonstrate that an establishment claim is literally false, the proponent must show that the study at issue does not support it or is unreliable. Id.

Ferring is correct that the superior cleansing efficacy claim is an establishment claim because it relies on the SEE CLEAR I study.¹ A genuine dispute of material fact remains, however, as to whether that study is reliable. See Gillette Co., 946 F. Supp. at 121. During discovery, Braintree produced a declaration from Dr. Douglas Rex, one of the co-authors of the study which states that

the SEE CLEAR I study and the article that [he] co-authored about it do not reliably support a marketing claim of Prepopik's superior cleansing

Dr. Rex's declaration with respect to the reliability of the SEE CLEAR I study also suggests that there is question of fact as to whether the presumption of consumer deception that accompanies literal falsity applies to that claim. See Cashmere, 284 F.3d at 314-15. Therefore Ferring is not entitled to summary judgment on either the Lanham Act or the Chapter 93A counterclaims based on the superior cleansing efficacy promotion.

¹ The Superior Cleansing Efficacy advertisement also cited the SEE CLEAR II study but, in that regard, the study merely concluded that Prepopik was non-inferior.

Order

For the foregoing reasons,

1. Ferring's motion for summary judgment (Docket No. 337) is **DENIED**,
2. Ferring's motion for summary judgment (Docket No. 338) is **DENIED** and
3. Braintree's motion for summary judgment (Docket No. 339) is, with respect Ferring's Lanham Act and Chapter 93A claims based on the Clean Freak advertisement and Ferring's trademark dilution claim, **ALLOWED** but otherwise **DENIED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated October 25, 2016